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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,176	01/20/2004	Robert H. Frater	4398-323	6667

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EXAMINER

LEWIS, AARON J

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/759,176

Applicant(s)

FRATER ET AL. 

Examiner

AARON J. LEWIS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 47-50 and 75-80 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 47-50 and 75-80 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 47-50, 75-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Venegas ('297).

As to claim 47, Venegas discloses a breathable gas mask arrangement, comprising: a mask shell having a portion (18) adapted to receive a supply of pressurized breathable gas (20) and a user side (12); a gusset portion (14) having a first side (32) attached to the user side of the shell and having a second side (18); a cushion (12) having a first portion constructed and arranged to attach to the second side of the gusset portion and a second portion (26) constructed and arranged to contact a user's face in use and provide a seal between the mask arrangement and the user's face; and a headgear (22) constructed and arranged to attach the mask shell to the user; wherein the gusset portion is constructed and arranged such that it can expand and contract to alter a distance between the mask shell and the cushion (col.4, lines 42-51), an interior of the gusset portion being exposed to the supply of pressurized breathable gas and having a projected area on the user's face  $A_g$  which is greater (col.4, lines 28-31) than an area  $A_c$  of contact of the cushion with the user's face such that the supply of pressurized breathable gas acting on the area  $A_g$  provides a component of a contact

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force  $F_c$  of the cushion on the user's face, and a ratio of  $A_g/A_c$  is greater than 1.00 (col.4, lines 28-31), a change in total force of the mask on the face  $F_m$  being generally directly proportional at a given operating pressure to a displacement of the mask shell toward the user's face (col.4, lines 47-51) from an initial seal position within a range of such mask shell displacement.

The difference between Venegas and claim 47 is a range of mask shell displacement of about 6-25 mm.

Venegas (col.4, lines 47-51) discloses expansion of the mask shell causing it to be pressed against a user's face with sufficient force to form an airtight seal; accordingly, it stands to reason that the abovementioned expansion of the mask shell includes movement towards a user's face in order to achieve the airtight seal. The amount of movement of the shell towards a user's face including a distance within a range of 6-25mm can be arrived at (i.e. adjusted using headgear 22 as disclosed at col.3, lines 57-59) through mere routine obvious experimentation and observation in dependence upon the patient's size, shape and age and comfort level with a given degree of tightness.

As to claim 48, Venegas (col.4, lines 47-51) as discussed above with respect to claim 47, discloses expansion of the mask shell causing it to be pressed against a user's face with sufficient force to form an airtight seal; accordingly, it stands to reason that the abovementioned expansion of the mask shell includes movement towards a user's face in order to achieve the airtight seal. The amount of movement of the shell towards a user's face including a distance within a range of 10-20mm can be arrived at (i.e. adjusted using headgear 22 as disclosed at col.3, lines 57-59) through mere routine

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obvious experimentation and observation in dependence upon the patient's size, shape and age and comfort level with a given degree of tightness.

As to claim 49, Venegas (col.4, lines 28-31) discloses the ratio of  $A_g/A_c$  to be 1.2-1.6 which includes the portion of the claimed range of 1.5-1.6.

As to claim 50, Venegas discloses the gusset portion (14) to include a single gusset having a flexible sidewall (figs.1-3) with a generally triangular cross-section when not exposed to the supply of pressurized breathable gas that balloons to a generally rounded cross-section (fig.2) when exposed to the supply of pressurized breathable gas. That is, the gusset portion being an expansible member (co.3, line 2) is fully capable of expanding outwardly in a manner which resembles a "generally rounded" cross section when inflated with pressurized breathable gas.

As to claim 75, Venegas (figs.1-3) discloses a mask assembly attachable to a user for receiving and supplying pressurized air to the user, comprising: a cushion (26) for contacting a user's face; and a suspension mechanism (14) axially movably supporting the cushion and exposed to the pressurized air to provide a first axial spring force to the cushion proportional to a pressure of the air.

Venegas lacks express disclosure of a second axial force on the cushion due to the pressurized air acting directly on the cushion which is at least 30% less than the first axial spring force; however, fig.4 of Venegas illustrates that the pressurized air acts through the suspension mechanism to provide a sealing force on the mask rather than acting directly on the cushion (26) to provide a sealing force. It stands to reason that any force on the cushion from the pressurized gas is negligible compared to the force

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on the cushion from through the suspension mechanism (14); consequently, any force from the pressurized gas that is acting directly on the cushion from the pressurized gas is at least 30% less than the force of the pressurized gas acting through the suspension mechanism (14).

Claim 76 is included in Venegas for the reasons set forth above with respect to claim 75.

As to claim 77, Venegas discloses the gusset portion (14) to include a single gusset having a flexible sidewall (figs.1-3) with a generally triangular cross-section when not exposed to the supply of pressurized breathable gas that balloons to a generally rounded cross-section (fig.2) when exposed to the supply of pressurized breathable gas. That is, the gusset portion being an expansible member (co.3, line 2) is fully capable of expanding outwardly in a manner which resembles a "generally rounded" cross section when inflated with pressurized breathable gas.

Claims 78-80 are substantially equivalent in scope to claims 75-77 and are included in Venegas for the reasons set forth above with respect to claims 75-77.

### ***Conclusion***


3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of the art is cited to show relevant mask assemblies.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (703) 308-0716. The examiner can normally be reached on 9:30AM-6:00PM M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
AARON J. LEWIS  
Primary Examiner  
Art Unit 3743

Aaron J. Lewis  
September 24, 2004